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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,695	09/30/2003	Robin D. Pierce	ADCI-073	5085

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EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,695	PIERCE ET AL.	
	Examiner	Art Unit	
	KAJ K. OLSEN	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,8-16,18,21 and 23-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,8-16,18,21 and 23-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/28/2010;7/27/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3, 6, 8-16, 18, 21, and 23-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Applicant has amended claims 1, 16, and 31 to specify that the polymer providing the hydrophilic domains is present in an amount from 0.01-2%. Applicant alleges that the specification (particularly p. 5, ll. 10-15, Table 1, and p. 20, ll. 20-25) provides support for this limitation. The examiner disagrees. Only p. 20, ll. 20-25 discuss a percentage of polyethylene glycol (1%), which wouldn't support the total claimed range. Although Table 1 specifies that "[i]nactive materials" can account for 0-2% of the conductive ink weight, there is nothing in the specification that would suggest that these inactive materials refer solely to the hydrophilic polymers of pp. 5 and 20. In fact, p. 20, l. 29 - p. 21, l. 5 appears to suggest that the inactive materials of Table 1 would be everything other than the hydrophilic polyethylene glycol polymer providing the hydrophilic domains. Moreover, there still wouldn't be any support for the now claimed lower end of 0.01%.

4. With respect to claim 35 and 36, the original filed disclosure also never explicitly set forth an electrode having less polymer than enzyme. In particular, applicant only shown example of the amount of polymer was 1% whereas the enzyme was typically present in amounts from 0-1% by weight (Table 1). There are no explicit example of a conductive ink containing a non-zero amount of polymer where there is less polymer than enzyme.

5. The previous 112 first and second paragraph rejections were withdrawn in view of the removal of "non-reactive" from the claims.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 3, 6, 8-11, 29, 31, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (USP 6,103,033) in view of any one or more of Charlton et al (USP 5,798,031), Maley et al (USP 5,770,028), and/or Hoenes et al (USP 5,122,244) with evidence from Ikeda (5,582,697). Maley, Hoenes, and Ikeda are being cited and relied on for the first time with this office action.

8. Say discloses a biosensor for determining a concentration of an analyte in a liquid sample (e.g. glucose in blood) comprising an electrode support 50, an arrangement of electrodes (58, 60, 62) disposed on the electrode support, the arrangement of electrodes comprising at least one working electrode 58 and a second electrode (60, 62), the working electrode comprising conductive ink and at least one enzyme and mediator in it. See col. 20, ll. 10-29 where Say teaches placing the catalyst in the electrode ink and see col. 19, l. 43 - col. 20, l. 9 where Say

considers the mediator to be part of the catalyst as well. Say discloses first and second conductive tracks 52 leading from the working and second electrode to an electrical contact 49. See fig. 11 for example. Say also discloses that the two electrodes can be separated by less than about 200 microns (col. 11, ll. 22-36). Say does not explicitly disclose the use of a polymer that provides a hydrophilic domain. Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Charlton for the sensor of Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Say would inherently create hydrophilic domains in the conductive ink. In addition, Hoanes discloses an alternate electrode containing both conductive particles and enzymes (like say) and teaches that the electrode should contain a small amount of hydroxyethyl cellulose, which is a polymer having hydrophilic domains (col. 19, ll. 17-27). Maley is drawn to an alternate measuring electrode comprising a mixture of conductive particles and enzymes (like Say) and teaches that it is desirable to add a surfactant material to the electrode in order to facilitate wetting of the electrode. See col. 15, ll. 22-63. A surfactant having a high hydrophilic lipophilic balance (HLB) that facilitate aqueous sample uptake inherently provides hydrophilic domains. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of either Hoanes or Maley for the biosensor of Say so as to facilitate the wicking up of sample to the electrode. As to Maley applying its surfactant after the electrode is dry (as opposed to in the conductive ink itself), applicant evidences that the

eventually electrode will be dried prior to use of the electrode anyway (p. 22, ll. 27 and 28). Hence, whether or not the hydrophilic domains are provided to the ink itself or after the ink has dried would not alter the prepared biosensor having a dried ink containing hydrophilic domains.

9. With respect to the new limitation requiring the polymer being present in between 0.01-2% by weight, finding the appropriate amount of hydrophilic polymer or surfactant that provides the desired level of wetting, including the use of 0.01-2% by weight, would have required only routine skill in the art. Moreover, Hoanes appears to teach that only a small amount of hydrophilic polymer is necessary for inducing the desired hydrophilic domains for the electrode (col. 19, ll. 17-27). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize less than 2% of the polyethylene glycol or surfactant of Charlton or Maley as suggested by Hoanes because only a small amount of hydrophilic material is necessary for improving the sensor wetting properties.

10. With respect to the mediator composition, the osmium complexes of col. 19, ll. 12-33 of Say for example read on the defined organometallic and organic compounds of the claims.

11. With respect to the use of small sample volumes, see Say, col. 4, ll. 8-14.

12. With respect to the electrode area, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize electrode areas of from 0.5 mm^2 to 5 mm^2, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In particular, larger electrodes would provide greater sensitivity while smaller electrodes would hold the overall size of the sensor down. Finding the appropriate area that balances these competing concerns requires only routine skill in the art.

13. With respect to the presence of a third or trigger electrode, Say discloses a third electrode 62 (col. 14, ll. 44-50) and this would read on the defined third electrode. Although not disclosed as being a trigger electrode, the term "trigger" merely defines how applicant intends to utilize the electrode and does not further define the structure of the electrode itself. This is evidenced by Ikeda where a given reference electrode for the sensor can be utilized as a trigger electrode as well (col. 8, ll. 29-37) indicating that triggering is just the intended use of the electrode and doesn't further define it.

14. With respect to the set forth fourth electrode, see Say fig. 6 and col. 14, ll. 29-43. With respect to the electrode having a trigger function, this again defines how the electrode is to be used and doesn't further define the structure of the electrode itself. See the discussion of Ikeda above.

15. With respect to the use of dehydrogenase, see Say col. 19, ll. 43-55.

16. With respect to claim 31 (those limitations not covered above), Say discloses that the biosensor can be made to contact a meter (i.e. control unit). See col. 13, ll. 28-40.

17. With respect to claims 35 and 36 (those limitations not covered above), because the hydrophilic polymer and enzyme are separately provided and provide differing function for the electrode, using differing amounts of each of the enzyme and polymer to tailor the electrodes sensitivity and fluid wetting ability would have required only routine skill in the art. As to the use of more enzyme than polymer, Hoanes teaches that only a small percentage of hydrophilic polymer is necessary for successful wetup (col. 19, ll. 17-27), so it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an amount of

the polymer of Charlton or Maley less than the amount of enzyme because very little polymer appears to be necessary for successful electrode wetup.

18. Claims 1, 3, 6, 8-16, 18, 21, 23-31, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and any of Charlton, Maley, and/or Hoanes and with evidence from Ikeda.

19. Feldman discloses a biosensor (col. 1, ll. 13-14) having: an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and at least one reagent incorporated in the working electrode (col. 21 , ll. 28- 31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38). Feldman does not disclose placing the enzyme and the mediator into a conductive ink. Say (who has the same assignee as Feldman) discloses that in an effort to minimize leaching of the catalysts (i.e. the enzyme and mediator), the catalysts can be incorporated directly into the conductive ink of the sensor. See col. 19, l. 56 - col. 20, l. 29, especially col. 20, ll. 10-29. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Say for the biosensor of Feldman so as to obviate the need for

multiple coating steps for the electrode as well as keeping the enzyme from leaching away. Keeping the mediator and enzyme from leaching away was a particular concern of Feldman (see abstract for example) and the suggestion of incorporating the enzyme and mediator into the conductive ink by Say represents an alternate or additional way to prevent such a leaching from occurring.

20. Neither Feldman nor Say explicitly disclose the use of a polymer that provides hydrophilic domains in the conductive ink. Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. Moreover, both Maley and Hoanes render obvious the addition of a polymer having hydrophilic domains to an electrode in order facilitate the wetting up of the electrode. See Maley col. 15, ll. 22-63 and Hoanes col. 19, ll. 17-27. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of any of Charlton, Maley, or Hoanes for the sensor of Feldman and Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Feldman and Say would inherently create hydrophilic domains in the conductive ink.

21. With respect to the various dependent claims, see the discussion of Feldman from the previous 10/8/2009 office action and of Say and Ikeda above.

22. Claims 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say in view of any of Charlton, Maley, or Hoanes as set forth for claims 1 and 31 above, and in further view of Yamashita et al (USP 5,472,590).

23. Say and any of Charlton, Maley, or Hoanes set forth all the limitations of claims 32 and 34, but did not explicitly recite the use of polyethylene glycol as the hydrophilic polymer. However, polyethylene glycol is a subset of the broader polymer class of polyethylene oxide utilized by Charlton. In particular, polyethylene glycol is polyethylene oxide where the terminal groups of the polymer are hydroxyl units. Yamashita explicitly teaches that polyethylene glycol is a particular useful choice of polyalkylene oxide polymer when the property being desired is a hydratable substance (i.e. "water-keeping property"). See abstract and col. 5, ll. 51-63 of Yamashita. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the polyethylene glycol as taught by Yamashita for the polyethylene oxide suggested by Charlton, for the surfactant of Maley, or the hydrophilic polymer of Hoanes for the biosensor of Say and Charlton because polyethylene glycol has been demonstrated as being a suitable choice of hydratable polymer for sensor applications.

24. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and any of Charlton, Maley, or Hoanes as set forth for claims 1, 16, and 31 above, and in further view of Yamashita.

25. These claims are further rejected over Yamashita for the reasons set forth above.

Response to Arguments

26. Applicant's arguments filed 4/6/2010 have been fully considered but they are not persuasive. With respect to the arguments concerning the previous 112 first and second paragraph rejections as well as the rejections relying on either Mizutani or Saby, these rejections have been withdrawn in view of the amendment.

27. Applicant continues to traverse the examiner's further use of Charlton for the reasons set forth in previous applicant responses. The examiner addressed all the previous arguments in previous office actions, so no further comment on those arguments should be necessary. Moreover, one of the applicant's main arguments is that Charlton wouldn't motivate one to includes a hydrophilic domain into the ink itself because it teaches placing the hydrophilic polymer over the electrode and not within. Although that argument was not persuasive (see the various previous office actions), the examiner is including in this office action the teachings of Maley and Hoanes clearing showing that a hydrophilic species designed to facilitate the wetting of an enzyme in a conductive ink should be included within the electrode itself when the electrode itself contains the enzyme (like in Say), and not on top of the enzyme containing electrode as the applicant has suggested.

28. Furthermore, the examiner is including the use of Ikeda as evidence in support of the examiner's previous statement that specifying an electrode is a triggering electrode doesn't further define the actual electrode.

29. Applicant's arguments concerning the further use of Yamashita appear to rely on the perceived failings of the earlier rejection involving Say and Charlton. Because those earlier arguments were not persuasive, these further arguments are similarly unpersuasive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795

August 9, 2010